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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/728,577 | 12/05/2003 | Scott A. Burton | 57260US003 | 8901 |

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| EXAMINER | |
|---|---|
| FUBARA, BLESSING M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/30/2007 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/728,577 | BURTON ET AL. | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26,54,55,60,71 and 74-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,54,55,60,71 and 74-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/04/07, 11/08/07, 11/01/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 09/07/07; and IDS filed 11/08/07, 11/01/07 and 09/04. Claims 27-53, 56-59, 61-70, 72 and 73 are cancelled. Claims 1-26, 54, 55, 60, 71 and 74-76 are pending.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-26, 54, 55, 60, 71 and 74-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

3. Amended claim 1 and new claim 74 recite solubility of silver compound without designating the solvent. However, the original specification described solubility of the silver compound in water (see page 2, lines 3 and 13 and page 9, line 9). Therefore, the original specification does not envision solubility of silver compound in any solvent other than water.

The above rejection may be overcome by removing the new matter from the claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-17, 20-23, 54, 55 and 74-76 remain/are are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenzi et al. (US 6,217,889).

Lorenzi discloses compositions comprising synthetic polymer such as polyamides, polyurethane foam and polyesters (column 4, lines 49-64), which is constituent of the creped non-woven layer of the composition in the form of film of sponges (column 4, lines 12,13; column 6, lines 48-51; column 8, lines 37-40) and meeting claims 1, 2, 7-12, 16, 20, 21, 54; therapeutic agents such as silver nitrate antiviral agents (column 31, line 64) or zinc oxide sunscreen actives (column 32, lines 28 and 29) meeting claim 1; composition may also contain cationic lathering surfactants (column 14, lines 32-46) meeting claims 13 and 14; the

composition may also contain dyes or preservatives (Example 8) and silicone antifoaming agent (column 24, line 1) meet the requirements of claim 15. The emulsion of Lorenzi is an inverse emulsion (column 23, lines 45 and 46). Combinations of polymers are contemplated (column 4, lines 54) meet claim 17. Lorenzi suggests that polymeric gelling agents in the form of particles can be used (column 35, lines 21-23 and 28) meeting the particle requirement of claim 1. Claim 55 is the intended use of the composition so that Lorenzi meets the claim. Regarding the microparticles, it is noted that there is no demonstration in applicant's specification that the particle size of 10 microns provides unexpected results. The solubility parameter recited in claim 1 for the silver compound is inherent to the silver compound because a compound and its properties are not separable. Regarding new claim 74 where the microparticles comprise polyquaternary amine containing compound, it is noted that Lorenz teaches the presence of quaternary amine compounds (column 14, line 33 to column 16, line 61) and also polyquaternium compounds (column 24, lines 27-65). Regarding claims 75 and 76 and the amounts of the bioactive agent, it is within the technical grasp of the artisan to use amounts of the bioactive agents that would produce the desired effects. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the formulation of Lorenzi with suggestion in Lorenzi to use particles of gelling agents. In the absence of factual showing, the particle size recited in claim 1 does not patentably distinguish the claimed invention over Lorenzi.

***Response to Arguments***

7. Applicant's arguments filed 09/07/07 have been fully considered but they are not persuasive.

Applicant argues that Lorenzi's personal care composition is different from the polymer composition of the claims formed by "a method that involves combining an organic polymer matrix, in an inverse emulsion comprising absorbent hydrophilic microparticles comprising an amine organic polymer, a bioactive agent and an optional foaming agent in a manner to produce polymer mixture comprising the organic polymer matrix ...microparticles."

Response: Applicant argues the process of preparing the product and product by process claims are not limited to the manipulations of the steps, but to the structure implied by the steps. In the present case, Lorenzi teaches the polymer composition as described in the rejection differing only in the size of the particles.

8. Claims 1-26, 54, 55, 60 and 71 and new claim 75 remain/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Asmus (US 5,270,358).

Asmus discloses a composite (column 40, lines 16-45) as a wound care product (column 44, lines 17-30) meeting claims 60 and 71; the composite contains a gel at 1-95 wt % and having a size of 1-600 microns (column 19, lines 16-20) with the particle size encompassing the claimed particle size of 10 micron or less in claims 1-5; the composite also contains hydrocolloid (column 6, line 54 to column 8, line 50) meeting limitation of a hydrophilic polymer and a swelling agent; the composite composition contains antimicrobial agents such as silver oxide (column 12, lines 27-44) meeting the requirement for bioactive agent of claim 1; the pressure sensitive adhesive (column 4, lines 53 to column 6, line 29) meeting the limitation of matrix polymer of claim 1; the presence of water (column 9, lines 66-67) meets claim 26; tackifiers and crosslinkers and stabilizers (column 6, lines 3) meet claim 15. Claim 54 is an article of the

composition and medical article recited in the preamble is the intended use of the composition so that Asmus meets claim 54. Claim 54 is met because the claim is an intended use of the composition. The solubility parameter recited in claim 1 for the silver compound is inherent to the silver compound because a compound and its properties are not separable. Claim 1 is a product by process claim and patentability of the claim is based on the product and not on the manipulations of the process steps. Regarding new claim 75, it is within the technical grasp of the artisan to use amounts of the bioactive agents that would produce the desired effects. In the alternate, the particle size of Asmus renders obvious the recited particle size since the disclosed particle size overlaps the recited particle size.

***Response to Arguments***

9. Applicant's arguments filed 09/07/07 have been fully considered but they are not persuasive.

Applicant argues that a) not all silver salts have a solubility of at least 0.1 gram/liter and makes reference to the 64$^{th}$ edition of the CRC handbook at page B-137 provided as exhibit A and specifically mentions silver oxide having a solubility of 0.013 gram/liter in cold water and 0.053 gram/liter in hot water, and silver sulfate having solubility of at least 0.1 gram/liter, and silver stearate having solubility of 0.06 gram/liter. b) Asmus discloses silver compounds having a solubility of at least 0.1 gram/liter in addition to numerous other antimicrobial agents, but does not exemplify or "provide enabling disclosure of the presently claimed species" so that Asmus does not anticipate the claims. c) There is no suggestion in Asmus to select silver compound having a solubility of at least 0.1 gram/liter from the wide variety of antimicrobial agents and

requires the examiner to point to the section of the prior art that discloses the claimed polymer composition.

Response: Regarding a) and solubilities of the silver compound from the CRC handbook, the solubility parameters are still the properties of those silver compounds whether the solubility is determined in cold water or hot water. Asmus discloses silver salt for which applicant admits the solubility to be at least 0.1 gram/liter and this solubility is inherent to silver nitrate and solubility is a property of the salt an element or compound. It is also brought to applicant's attention that the claim generically claims a silver compound and applicant's own admission appears to question applicant's claim to all silver compounds having the claimed solubility. However, regarding b), it would be obvious to use any of the salts of silver as claimed by Asmus in claim 30. The CRC handbook indicates that silver oxide is soluble in other solvents without stating any amount and the amendment of the claim 1 deleting the solubility in water may support the solubility of silver oxide in other solvents to be at least 0.1 gram/liter. Regarding c), claim 1 requires the polymer to be polyquaternary amine, polylactam, polyamide or mixtures and one of the hydrocolloid polymer in Asmus is a polyvinyl lactam (column 6, lines 64 and 65), meeting the requirements of claim 1. Silver compound in Asmus (claim 30, column 12, lines 41 and 42) is silver oxide or silver salts. Product by process claims are not limited to the manipulations of the steps, but to the structure implied by the steps. In this case, Asmus teaches the product.

***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-26, 54, 55, 60 and 71 and new claims 74-76 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-51, 53-55, 58-93; 1-34, 1-44 of copending Application Nos. 10/728,439; 10/387,236; 10/728,446. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims and the co-pending claims are directed to composition that contain bioactive silver compounds, polymer matrix, foaming agent and the composition is used as care for wounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-26, 54, 55, 60 and 71 and new claims 74-76 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/729,114 in view of Asmus (5,270,358). The copending application discloses the composition of the examined claims except that the claims

are silent as to whether the composition is an emulsion or not. However, Asmus discloses an emulsion that comprises the composition of the copending application for use in wound care. Therefore, it would have been obvious to use the composition of the co-pending application as an emulsion in wound treatment.

This is a provisional obviousness-type double patenting rejection.

*Applicant proposes to address the provisional obviousness-type double patenting rejection when allowable subject matter is identified. However, the rejection is maintained.*

No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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